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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,560	06/21/2006	Ian Alexander Graham	7730-72576-01	9611
24197 7590 10/02/2007 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER BUI, PHUONG T	
			ART UNIT 1638	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/564,560

**Applicant(s)**

GRAHAM ET AL.

**Examiner**

Phuong T. Bui

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/12/06</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed August 20, 2007. Applicant elects Group I and SEQ ID NO:3 with traverse. Applicant requests rejoinder of all seven groups and that the claims relate to a single inventive concept because the fatty acid elongases described in USPN 7038112 were isolated from *Arabidopsis* while the fatty acid elongases claimed here were from *Thalassiosira*. Applicant's traversals have been considered but are deemed unpersuasive for the following reasons. Once the product claims are found allowable, rejoinder of methods to make and methods to use containing all the limitations of the product claims will be considered (37 CFR 1.104). The claimed invention lack the same or corresponding technological feature because fatty acid elongases were known in the art, and the claims allow for sequence modifications such that they lack novelty in view of the cited prior art. Furthermore, while a search of the prior art of one group may overlap with that of another group, they are not coextensive of each other and thus would represent undue burden on Office resources. Claims 1-22 are pending. Claims 1-12 to the extent of SEQ ID NO:3 encoding SEQ ID NO:6 are examined in the instant application. This restriction is made FINAL. SEQ ID NO:3 encoding SEQ ID NO:6 was first disclosed in foreign priority document United Kingdom 0316629.5 filed July 16, 2003.

### **Claim Objections**

2. Claims 4 and 9 are objected to because of the following informalities: Claim 4 recites different algal species which do not reflect the election of SEQ ID NO:3. Claim 9(iv)-(vi) recites nonelected inventions.

Claims 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1(i) requires SEQ ID NO:3 while dependent claim 2 recites a nucleic acid molecule which anneals under stringent hybridization conditions to (i).

Appropriate correction is required.

### ***Drawings***

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because there are two Figures 1a and two Figures 7b. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Applicant is reminded that the specification must be amended accordingly to reflect any changes in the drawings.

New matter should be avoided.

### ***Sequence Listing***

4. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:3 and its corresponding amino acid sequence SEQ ID NO:6, it is unclear what region of SEQ ID NO:3 encodes SEQ ID NO:6. Clarification is needed.

***Information Disclosure Statement***

5. An initialed and dated copy of Applicant's IDS form 1449, filed January 12, 2006, is attached to the instant Office action.

***Claim Rejections - 35 USC § 112, second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims which recite "hybridizes" or "stringent hybridization conditions" are unclear because those skilled in the art define hybridization conditions differently. Page 22 of the specification gives examples of different hybridization conditions but the claims are not limited to any particular hybridization conditions. It is suggested that the claims recite the hybridization conditions.

In claims 1(iii) and 9(iii), "degenerate" would only apply to sequences encoding the amino acid sequence of SEQ ID NO:6. It does not apply to the nucleic acid sequence of SEQ ID NO:3.

In claim 5, it is unclear whether claim 5 is intended to be impermissibly broader than claim 1 or that the variant of claim 5 must hybridize to SEQ ID NO:3 of claim 1(ii).

The words "enhances" and "enhanced" in Claims 5 and 6 are relative terms lacking a comparative basis.

Claim 5 recites enhanced enzyme activity and dependent claim 6 recites enhanced fatty acid elongase activity. However, since the enzyme of Claim 5 must be fatty acid elongase, Claim 6 is a duplicate of Claim 5.

In claim 9, it is unclear why there are two Markush language recitations. Applicant should note that (iv)-(vi) are drawn to nonelected inventions. If Applicant is claiming SEQ ID NO:1 in combination with SEQ ID NO:10, 12 or 14, this will be treated as a combination/subcombination claim and (iv)-(vi) will also be restricted out as nonelected inventions.

Clarification and/or correction is required.

***Claim Rejections - 35 USC § 101 Utility***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility.

Applicant asserted that the nucleotide sequence SEQ ID NO:3 encoding SEQ ID NO:6 has fatty acid elongase activity. Applicant states that SEQ ID NO:3 was isolated from *Thalassiosira*. First of all, SEQ ID NO:3 does not appear to encode a complete protein. The polypeptide of SEQ ID NO:6 as encoded by SEQ ID NO:3 does not begin with an initiation codon, e.g., methionine. The specification does not disclose that SEQ ID NO:6 is a complete protein. In fact, in the certified copy of Applicant's priority document filed January 20, 2006, Fig 1b corresponding to SEQ ID NO:3 indicates that Applicant is unsure whether SEQ ID NO:3 is a complete open reading frame (see

Art Unit: 1638

statement "complete ORF?"). While a complete protein, such as an enzyme, inherently possesses region(s) essential for enzymatic activity, it is unclear as to whether SEQ ID NO:3 which encodes a partial protein would possess the regions essential for fatty acid elongase activity. Applicant does not indicate whether SEQ ID NO:3 contains all the regions necessary for the asserted activity. Applicant provided no evidence that SEQ ID NO:3 encodes a protein having fatty acid elongase activity. Absent activity, it is unclear how one would use the claimed invention. Thus, it does not appear that the asserted utility of fatty elongase is credible.

In addressing claims drawn to a sequence which hybridizes to SEQ ID NO:3, since SEQ ID NO:3 and a polynucleotide encoding SEQ ID NO:6 lack utility for the reasons set forth above, sequences having less than 100% sequence identity to these sequences would also lack utility. Applicant should note that no working examples of a sequence which hybridizes to SEQ ID NO:3 are set forth in Applicant's disclosure.

Additionally, there also is no well-established utility for SEQ ID NO:3 and a sequence encoding SEQ ID NO:6. SEQ ID NO:3 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed invention lacks utility under current utility guidelines. (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

***Claim Rejections - 35 USC § 112, first paragraph***

10. Claims 1-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well

Art Unit: 1638

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Furthermore, these claims are not enabled because they encompass unspecified base substitutions, deletions, additions, and combinations thereof while retaining or enhancing fatty acid elongase activity. One skilled in the art would not be able to predictably determine which sequences which hybridizes to SEQ ID NO:3 would retain activity, or what modifications would result in enhanced fatty acid elongase activity. Most mutations would likely abrogate activity, assuming that SEQ ID NO:3 encodes a polypeptide which has enzyme activity. Moreover, while one skilled in the art can readily make mutations to SEQ ID NO:3 or a sequence encoding SEQ ID NO:6, further guidance is needed as to what mutations would not abrogate activity or would enhance activity. Applicant provided no working example of any mutant sequences which has the asserted activity. Neither the state of the prior art nor Applicant's disclosure provides guidance as to what single amino acid residue at what position would enhance enzyme activity. Accordingly, the claimed invention cannot be practiced without excessive and undue experimentation as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 112, first paragraph***

11. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims reciting "hybridizes" or "variant"



lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass fatty acid elongase sequences from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:3 isolated from *Thalassiosira*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and fatty acid elongase sequences from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Mukerji et al. (USPN 6677145 (A)). Since the hybridization conditions are not recited,

Art Unit: 1638

"variant" allows for any sequence modification, and "enhances" lacks a comparative basis, the claims read on any fatty acid elongase. Mukerji teaches a nucleic acid sequence encoding a fatty acid elongase isolated from *Thalassiosira pseudonana*, as well as the cell, plant and seed containing said sequence. Accordingly, Mukerji anticipated Applicant's claimed invention as commensurate in scope with the claims.

**Remarks**

14. No claim is allowed. SEQ ID Nos. 3 and 6 are free of the prior art.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

09/19/07

  
**PHUONG T. BUI**  
**PRIMARY EXAMINER**

Phuong T. Bui